

(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 199867267 B2
(10) Patent No. 744506

(54) Title
Pump system with error detection for clinical nutrition

(51)⁶ International Patent Classification(s)
A61M 005/168

(21) Application No: 199867267 (22) Application Date: 1998 .02 .24

(87) WIPO No: W098/46294

(30) Priority Data

(31) Number (32) Date (33) Country
120651 1997 .04 .11 IL

(43) Publication Date : 1998 .11 .11

(43) Publication Journal Date : 1998 .12 .24

(44) Accepted Journal Date : 2002 .02 .28

(71) Applicant(s)
Societe Des Produits Nestel S.A.

(72) Inventor(s)
Swi Barak

(74) Agent/Attorney
BALDWIN SHELSTON WATERS,Level 21,60 Margaret Street,SYDNEY NSW 2000

(56) Related Art
US 4530696
US 4846792
US 5423743

OPI DATE 11/11/98 APPLN. ID 67267/98
 AOJP DATE 24/12/98 PCT NUMBER PCT/EP98/01130



AU9867267

27

(51) International Patent Classification 6 : A61M 5/168		A1	(11) International Publication Number: WO 98/46294
			(43) International Publication Date: 22 October 1998 (22.10.98)
(21) International Application Number: PCT/EP98/01130		(81) Designated States: AU, BR, CA, CN, ID, JP, MX, RU, VN, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 24 February 1998 (24.02.98)			
(30) Priority Data: 120651 11 April 1997 (11.04.97) IL		Published: With international search report.	
(71) Applicant: SOCIETE DES PRODUITS NESTLE S.A. [CH/CH]; P.O. Box 353, CH-1800 Vevey (CH).			
(72) Inventor: BARAK, Swi; Harakafet Street 5, 30660 Caesarea (IL).			
(74) Agent: McCONNELL, Bruce; Société des Produits Nestlé S.A., P.O. Box 353, CH-1800 Vevey (CH).			
(54) Title: PUMP SYSTEM WITH ERROR DETECTION FOR CLINICAL NUTRITION			
(57) Abstract : A pump for delivering a liquid from a container to a patient through a flow set. The pump includes a sensing means and a controller. The sensing means senses a parameter indicative of the pressure in the flow set. The controller has a computing and memory means for determining deviation of the parameter from a standard. Deviation is indicative of an error in the flow set. This enables supervising staff to be alerted. These errors may be incorrect assembly of the system or one of its components, inclusion in the system of an incorrect valve, impairment in the integrity of the flow set, and the existence of air bubbles in the system.			

Pump System With Error Detection for Clinical Nutrition

This invention relates generally to a pump system for administering liquids to a patient; for example medicinal or nutritional solutions. The liquids may be administered enterally or parenterally. The invention also relates to a pump for use in the system and
5 to methods of administering liquids to a patient.

Systems for administering liquids to a patient are widely used in clinical settings. All of these systems comprise a container for the liquid and a flow set for delivering the liquid to the patient. In general, the liquid is either allowed to drain through the flow set to the patient under the action of gravity or is pumped through the flow set. Systems
10 using pressure sleeves on the container are also used. Systems using a pump are referred to in this specification as "pump systems".

The rate of flow of the liquid through the system is usually set to a desired rate depending on the needs of the patient. In pump systems this may be achieved by controlling the pump rate. However, particularly when intended for intravenous
15 administration of liquids, it is important to ensure that there will be no back flow of liquid in the tubing, that is away from the patient. To prevent this, a one-way valve is typically installed in the flow set. Further, because the container is typically mounted on a stand it is necessary to ensure that free-flow of liquid due to the liquid head will not occur when the pump is at rest. For this purpose, the valve, in addition to being a one-
20 way valve, also needs to prevent free flow. Therefore the valve has a certain threshold pressure which is required to open it to allow flow of liquid. The threshold pressure is also known as the "cracking point". Pump systems containing such a valve are described in PCT Application WO 95/16480 and US. Patent 5,472,420. However, incorrect valves are occasionally connected in the flow sets with serious consequences.

25 It is also important to ensure that the flow set, which is typically provided as an integral disposable set, is correctly connected to the pump to avoid pumping of liquid in a reverse direction, away from the patient. This is often left to the supervising staff and errors do occur. Also, flow sets occasionally fail and this is often not noticed until too late.

30 It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.



- 1a -

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

It is an object of the present invention to overcome or ameliorate at least one of
5 the disadvantages of the prior art, or to provide a useful alternative.

Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

10 Accordingly, in one aspect, this invention provides a pump for delivering

11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
66
67
68
69
70
71
72
73
74
75
76
77
78
79
80
81
82
83
84
85
86
87
88
89
90
91
92
93
94
95
96
97
98
99
100
101
102
103
104
105
106
107
108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139
140
141
142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163
164
165
166
167
168
169
170
171
172
173
174
175
176
177
178
179
180
181
182
183
184
185
186
187
188
189
190
191
192
193
194
195
196
197
198
199
200
201
202
203
204
205
206
207
208
209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243
244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259
260
261
262
263
264
265
266
267
268
269
270
271
272
273
274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
293
294
295
296
297
298
299
300
301
302
303
304
305
306
307
308
309
310
311
312
313
314
315
316
317
318
319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337
338
339
340
341
342
343
344
345
346
347
348
349
350
351
352
353
354
355
356
357
358
359
360
361
362
363
364
365
366
367
368
369
370
371
372
373
374
375
376
377
378
379
380
381
382
383
384
385
386
387
388
389
390
391
392
393
394
395
396
397
398
399
400
401
402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
467
468
469
470
471
472
473
474
475
476
477
478
479
480
481
482
483
484
485
486
487
488
489
490
491
492
493
494
495
496
497
498
499
500
501
502
503
504
505
506
507
508
509
510
511
512
513
514
515
516
517
518
519
520
521
522
523
524
525
526
527
528
529
530
531
532
533
534
535
536
537
538
539
540
541
542
543
544
545
546
547
548
549
550
551
552
553
554
555
556
557
558
559
560
561
562
563
564
565
566
567
568
569
570
571
572
573
574
575
576
577
578
579
580
581
582
583
584
585
586
587
588
589
590
591
592
593
594
595
596
597
598
599
600
601
602
603
604
605
606
607
608
609
610
611
612
613
614
615
616
617
618
619
620
621
622
623
624
625
626
627
628
629
630
631
632
633
634
635
636
637
638
639
640
641
642
643
644
645
646
647
648
649
650
651
652
653
654
655
656
657
658
659
660
661
662
663
664
665
666
667
668
669
670
671
672
673
674
675
676
677
678
679
680
681
682
683
684
685
686
687
688
689
690
691
692
693
694
695
696
697
698
699
700
701
702
703
704
705
706
707
708
709
710
711
712
713
714
715
716
717
718
719
720
721
722
723
724
725
726
727
728
729
730
731
732
733
734
735
736
737
738
739
740
741
742
743
744
745
746
747
748
749
750
751
752
753
754
755
756
757
758
759
760
761
762
763
764
765
766
767
768
769
770
771
772
773
774
775
776
777
778
779
780
781
782
783
784
785
786
787
788
789
790
791
792
793
794
795
796
797
798
799
800
801
802
803
804
805
806
807
808
809
810
811
812
813
814
815
816
817
818
819
820
821
822
823
824
825
826
827
828
829
830
831
832
833
834
835
836
837
838
839
840
841
842
843
844
845
846
847
848
849
850
851
852
853
854
855
856
857
858
859
860
861
862
863
864
865
866
867
868
869
870
871
872
873
874
875
876
877
878
879
880
881
882
883
884
885
886
887
888
889
890
891
892
893
894
895
896
897
898
899
900
901
902
903
904
905
906
907
908
909
910
911
912
913
914
915
916
917
918
919
920
921
922
923
924
925
926
927
928
929
930
931
932
933
934
935
936
937
938
939
940
941
942
943
944
945
946
947
948
949
950
951
952
953
954
955
956
957
958
959
960
961
962
963
964
965
966
967
968
969
970
971
972
973
974
975
976
977
978
979
980
981
982
983
984
985
986
987
988
989
990
991
992
993
994
995
996
997
998
999
1000
1001
1002
1003
1004
1005
1006
1007
1008
1009
1010
1011
1012
1013
1014
1015
1016
1017
1018
1019
1020
1021
1022
1023
1024
1025
1026
1027
1028
1029
1030
1031
1032
1033
1034
1035
1036
1037
1038
1039
1040
1041
1042
1043
1044
1045
1046
1047
1048
1049
1050
1051
1052
1053
1054
1055
1056
1057
1058
1059
1060
1061
1062
1063
1064
1065
1066
1067
1068
1069
1070
1071
1072
1073
1074
1075
1076
1077
1078
1079
1080
1081
1082
1083
1084
1085
1086
1087
1088
1089
1090
1091
1092
1093
1094
1095
1096
1097
1098
1099
1100
1101
1102
1103
1104
1105
1106
1107
1108
1109
1110
1111
1112
1113
1114
1115
1116
1117
1118
1119
1120
1121
1122
1123
1124
1125
1126
1127
1128
1129
1130
1131
1132
1133
1134
1135
1136
1137
1138
1139
1140
1141
1142
1143
1144
1145
1146
1147
1148
1149
1150
1151
1152
1153
1154
1155
1156
1157
1158
1159
1160
1161
1162
1163
1164
1165
1166
1167
1168
1169
1170
1171
1172
1173
1174
1175
1176
1177
1178
1179
1180
1181
1182
1183
1184
1185
1186
1187
1188
1189
1190
1191
1192
1193
1194
1195
1196
1197
1198
1199
1200
1201
1202
1203
1204
1205
1206
1207
1208
1209
1210
1211
1212
1213
1214
1215
1216
1217
1218
1219
1220
1221
1222
1223
1224
1225
1226
1227
1228
1229
1230
1231
1232
1233
1234
1235
1236
1237
1238
1239
1240
1241
1242
1243
1244
1245
1246
1247
1248
1249
1250
1251
1252
1253
1254
1255
1256
1257
1258
1259
1260
1261
1262
1263
1264
1265
1266
1267
1268
1269
1270
1271
1272
1273
1274
1275
1276
1277
1278
1279
1280
1281
1282
1283
1284
1285
1286
1287
1288
1289
1290
1291
1292
1293
1294
1295
1296
1297
1298
1299
1300
1301
1302
1303
1304
1305
1306
1307
1308
1309
1310
1311
1312
1313
1314
1315
1316
1317
1318
1319
1320
1321
1322
1323
1324
1325
1326
1327
1328
1329
1330
1331
1332
1333
1334
1335
1336
1337
1338
1339
1340
1341
1342
1343
1344
1345
1346
1347
1348
1349
1350
1351
1352
1353
1354
1355
1356
1357
1358
1359
1360
1361
1362
1363
1364
1365
1366
1367
1368
1369
1370
1371
1372
1373
1374
1375
1376
1377
1378
1379
1380
1381
1382
1383
1384
1385
1386
1387
1388
1389
1390
1391
1392
1393
1394
1395
1396
1397
1398
1399
1400
1401
1402
1403
1404
1405
1406
1407
1408
1409
1410
1411
1412
1413
1414
1415
1416
1417
1418
1419
1420
1421
1422
1423
1424
1425
1426
1427
1428
1429
1430
1431
1432
1433
1434
1435
1436
1437
1438
1439
1440
1441
1442
1443
1444
1445
1446
1447
1448
1449
1450
1451
1452
1453
1454
1455
1456
1457
1458
1459
1460
1461
1462
1463
1464
1465
1466
1467
1468
1469
1470
1471
1472
1473
1474
1475
1476
1477
1478
1479
1480
1481
1482
1483
1484
1485
1486
1487
1488
1489
1490
1491
1492
1493
1494
1495
1496
1497
1498
1499
1500
1501
1502
1503
1504
1505
1506
1507
1508
1509
1510
1511
1512
1513
1514
1515
1516
1517
1518
1519
1520
1521
1522
1523
1524
1525
1526
1527
1528
1529
1530
1531
1532
1533
1534
1535
1536
1537
1538
1539
1540
1541
1542
1543
1544
1545
1546
1547
1548
1549
1550
1551
1552
1553
1554
1555
1556
1557
1558
1559
1560
1561
1562
1563
1564
1565
1566
1567
1568
1569
1570
1571
1572
1573
1574
1575
1576
1577
1578
1579
1580
1581
1582
1583
1584
1585
1586
1587
1588
1589
1590
1591
1592
1593
1594
1595
1596
1597
1598
1599
1600
1601
1602
1603
1604
1605
1606
1607
1608
1609
1610
1611
1612
1613
1614
1615
1616
1617
1618
1619
1620
1621
1622
1623
1624
1625
1626
1627
1628
1629
1630
1631
1632
1633
1634
1635
1636
1637
1638
1639
1640
1641
1642
1643
1644
1645
1646
1647
1648
1649
1650
1651
1652
1653
1654
1655
1656
1657
1658
1659
1660
1661
1662
1663
1664
1665
1666
1667
1668
1669
1670
1671
1672
1673
1674
1675
1676
1677
1678
1679
1680
1681
1682
1683
1684
1685
1686
1687
1688
1689
1690
1691
1692
1693
1694
1695
1696
1697
1698
1699
1700
1701
1702
1703
1704
1705
1706
1707
1708
1709
1710
1711
1712
1713
1714
1715
1716
1717
1718
1719
1720
1721
1722
1723
1724
1725
1726
1727
1728
1729
1730
1731
1732
1733
1734
1735
1736
1737
1738
1739
1740
1741
1742
1743
1744
1745
1746
1747
1748
1749
1750
1751
1752
1753
1754
1755
1756
1757
1758
1759
1760
1761
1762
1763
1764
1765
1766
1767
1768
1769
1770
1771
1772
1773
1774
1775
1776
1777
1778
1779
1780
1781
1782
1783
1784
1785
1786
1787
1788
1789
1790
1791
1792
1793
1794
1795
1796
1797
1798
1799
1800
1801
1802
1803
1804
1805
1806
1807
1808
1809
1810
1811
1812
1813
1814
1815
1816
1817
1818
1819
1820
1821
1822
1823
1824
1825
1826
1827
1828
1829
1830
1831
1832
1833
1834
1835
1836
1837
1838
1839
1840
1841
1842
1843
1844
1845
1846
1847
1848
1849
1850
1851
1852
1853
1854
1855
1856
1857
1858
1859
1860
1861
1862
1863
1864
1865
1866
1867
1868
1869
1870
1871
1872
1873
1874
1875
1876
1877
1878
1879
1880
1881
1882
1883
1884
1885
1886
1887
1888
1889
1890
1891
1892
1893
1894
1895
1896
1897
1898
1899
1900
1901
1902
1903
1904
1905
1906
1907
1908
1909
1910
1911
1912
1913
1914
1915
1916
1917
1918
1919
1920
1921
1922
1923
1924
1925
1926
1927
1928
1929
1930
1931
1932
1933
1934
1935
1936
1937
1938
1939
1940
1941
1942
1943
1944
1945
1946
1947
1948
1949
1950
1951
1952
1953
1954
1955
1956
1957
1958
1959
1960
1961
1962
1963
1964
1965
1966
1967
1968
1969
1970
1971
1972
1973
1974
1975
1976
1977
1978
1979
1980
1981
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
2025
2026
2027
2028
2029
2030
2031
2032
2033
2034
2035
2036
2037
2038
2039
2040
2041
2042
2043
2044
2045
2046
2047
2048
2049
2050
2051
2052
2053
2054
2055
2056
2057
2058
2059
2060
2061
2062
2063
2064
2065
2066
2067
2068
2069
2070
2071
2072
2073
2074
2075
2076
2077
2078
2079
2080
2081
2082
2083
2084
2085
2086
2087
2088
2089
2090
2091
2092
2093
2094
2095
2096
2097
2098
2099
2100
2101
2102
2103
2104
2105
2106
2107
2108
2109
2110
2111
2112
2113
2114
2115
2116
2117
2118
2119
2120
2121
2122
2123
2124
2125
2126
2127
2128
2129
2130
2131
2132
2133
2134
2135
2136
2137
2138
2139
2140
2141
2142
2143
2144
2145
2146
2147
2148
2149
2150
2151
2152
2153
2154
2155
2156
2157
2158
2159
2160
2161
2162
2163
2164
2165
2166
2167
2168
2169
2170
2171
2172
2173
2174
2175
2176
2177
2178
2179
2180
2181
2182
2183
2184
2185
2186
2187
2188
2189
2190
2191
2192
2193
2194
2195
2196
2197

a liquid from a container to a patient through a flow set, the pump including:
a sensing means for sensing a parameter indicative of the pressure in the flow set; and
a controller having a computing and memory means for determining
5 deviation of the parameter from a standard, the deviation being indicative of an error in the flow set.

It has been surprisingly discovered that, by measuring the pressure in the flow set and comparing it to a standard, errors in the system may be detected. This enables supervising staff to be alerted. These errors may, for example, be
10 incorrect assembly of the system or one of its components, inclusion in the system of an incorrect valve, impairment in the integrity of the flow set, and the existence of air bubbles in the system.

In another aspect, this invention provides a pump system for administering a liquid from a container to a patient, the system comprising:

15 flow set comprising a tubing set connectable at one end to the container for delivery of liquid to the patient, and a one-way valve system coupled to the tubing set which permits liquid flow to the patient when a pressure differential over the valve exceeds a threshold pressure, and which prevents back flow;

a pump as defined above coupled to the tubing set.

20 Preferably, the controller causes the pump, during operation of the pump, to enter into a test phase at selected intervals, the test phase comprising a first test sequence in which the pump propels a first amount of liquid in a first direction through the flow set, and a second test sequence in which the pump propels a second amount of liquid through the flow set in a second direction, opposite the
25 first. The sensing means senses the parameter during the first test sequence and the second test sequence.

The valve system preferably comprises a valve having a liquid flow path sealed by a resilient membrane, the membrane being deformable in a desired flow direction at or above a threshold pressure for opening perforations in the
30 membrane to permit flow. Further, the valve preferably has a support preventing the membrane from deforming sufficiently in an opposite flow direction for preventing back flow.

In further aspect, this invention provides a method for administering a liquid from a container to patient using a pump system, the method comprising:

35 pumping liquid through a flow set from the container to the patient through a one-way valve system which permits flow to the patient when the

pressure differential over the valve system exceeds a threshold pressure, and which prevents back flow; and

intermittently entering a test phase comprising

pumping a first test amount of liquid in a first direction and then pumping

5 a second test amount of liquid in an opposite direction,

sampling a parameter indicative of pressure within the flow set during pumping of the first test amount of liquid and during pumping of second test amount of liquid, and

10 comparing the sampled parameters to a standard and, upon determining a difference of selected magnitude between the sampled parameters and the standard, indicating the existence of an error in the pump system.

The error which is diagnosed by the system, may, for example be:

the impairment of liquid flow through the flow set as a result of an occlusion, a rupture or a hole in the tubing, or disengagement of components of
15 the flow set, etc.;

incorrect engagement of the pump with the flow set, for example engagement in a reverse direction;

the use of incompatible components in the flow set, for example the use of an improper valve having improper flow specifications; or

20 changes in the flow parameters of the valve during operation, for example the existence of gas bubbles or gas pockets in the tubing; etc.

The present invention also provides a flow set for use in the system of the invention.

Embodiments of the invention are now described, by way of example only, with reference to the drawings in which:

Figure 1 is a schematic illustration of a pump system;

Figure 2A is a longitudinal cross-sectional view of a valve for use in the system of Figure 1 in a rest state;

Figure 2B is a longitudinal cross-sectional view of the valve of Figure 2A
30 in an operational state;

Figure 3A is a graph of the flow of liquid versus time during a test phase of the pump system; and

Figure 3B is a graph of the pressure build-up versus time during a test phase of the pump system.

35 A pump system 10 is illustrated in Fig. 1. The pump system 10 comprises a pump 14 with a control unit 15, and a flow set 12. The pump 14 is preferably a

peristaltic pump but any type of pump which is able to pump liquid at controlled flow rates suitable for clinical applications may be used. The control unit 15 typically comprises a control panel 15a which has a display 15b and a key pad 15c. The key pad 15c may be used for manual control of the pump, data entry, and the like. The control unit 15 also includes a microprocessor (not shown) for controlling and activating the pump and for data storage. A memory (not shown) may be associated with, or be incorporated in, the microprocessor. If desired, the control unit 15 may also include an audio, visual or dual alarm signalling means.

The flow set 12 is made up of a tubing set 16 which is connected to a liquid container 18 at one end and a connector 20 at the other end. A drip chamber 21 and a one-way valve 22 are coupled to the tubing set 16 between its ends. In this embodiment, the drip chamber 21 is positioned beneath the liquid container 18, upstream from the pump 14. The one-way valve 22 is positioned downstream from the pump 14. As is conventional, the connector 20 may be connected to a catheter, an enteral feeding tube, etc. When not in use, the free end of the connector 20 is covered by a cover 26.

The pump 14 is coupled to the tubing set 16 and is able to pump liquid in either direction. Therefore, from the container 18 to the connector 20 (the forward direction), and towards the container 18 (the reverse direction).

The pump 14 also includes a sensing means for sensing a parameter indicative of the pressure in the flow set 12. The sensing means (not shown) is conveniently a tube diameter gauge which measures the diameter of the tubing set 16. Then, using the known resiliency of the tubing set 16, the pressure in the tubing set 16 may be determined by the microprocessor. The tube diameter may for example, be a strain gauge, an optical sensor, and the like. Alternatively, other known means of determining pressure in the tubing set 16 may be used. For example, conventional pressure gauges may be connected into the tubing set 16. The pressure parameter is preferably repeatedly sampled at short time intervals so that a curve of pressure change with time may be developed.

The one-way valve 22, shown in cross-section in Fig. 2, has a housing 30 formed of a first housing member 32 and a second housing member 34. The first housing member 32 has a recess in it into which the second housing member 34 is accommodated in a sealed manner. The second housing member 34 also has a recess in it so that a chamber 35 is defined between the first and second housing members 32, 34.

The first housing member 32 has an inlet tube 36 which is connected to

the chamber 35 by means of an entry port 37. An annular rim 38 projects into the chamber 35 from the floor of the recess of the first housing member 32, about entry port 37. The second housing member 34 has an outlet tube 39 which is connected to the chamber 35 by means of an exit port 40. Both the inlet tube 36 and the outlet tube 39 are sized to be sealingly engaged by the tubing set 16. 5 which permits liquid to flow from the chamber.

The first housing member 32 has an annular shoulder 41 projecting from the floor of its recess at the circumference of its recess. The annular shoulder 41 and the annular rim 42 of the second housing member 34, when the second 10 housing member 34 is fitted in the recess of the first housing member 32, form an annular clamp.

A resilient membrane 44 is clamped between the annular shoulder 41 and the annular rim 42 in the annular clamp. In the rest state of the valve 22 shown in Fig 2A, the membrane rests on the annular rim 38 projecting from the first 15 housing member 32. The membrane 44 is made of a resilient flexible material, typically sterilisable material such as silicon, rubber or any other suitable material. The membrane 44 has a plurality of slits 46 (two shown in this cross-sectional view) which, in the rest state shown in Fig. 2A, are closed and do not permit flow of liquid through it.

When liquid is propelled through the inlet tube 36, the membrane 44 is stretched and deflected as shown in Fig. 2B. Once a selected threshold pressure differential is reached and the membrane 44 is sufficiently stretched, the slits 46 20 widen and open to allow flow of liquid from the inlet tube 36, through the chamber 35, to the outlet tube 39. The flow is represented by the arrows in Fig. 2B. Typically, the membrane 44 is designed so that slits 46 will open only when the pressure differential over the membrane exceeds about 20 kPa. This prevents undesired free flow of the liquid from the container 18, which in a clinical setting is typically placed on a stand of a height of about 2 metres.

For flow in the reverse direction, the membrane 44 cannot deflect 30 sufficiently since it is held against the floor of the recess of the first housing member 32. Therefore the valve 22 also prevents back flow of liquid.

In use, the control unit 15 causes the pump 14 to operate in a duty cycle which has an administration phase and a test phase. The test phase is entered at selected, intermittent intervals. Typically, test phase is entered immediately after 35 the pump system 10 has been set up, prior to initiation of the first administration phase. Thereafter, the test phase is entered at selected intervals, which may be

randomly selected, between consecutive administration phases. Thus, the pump 14 may operate in a duty cycle of a first test phase, followed by an administration phase and then repeatedly through test phases and administration phases. In general, the test phases are of much shorter duration than the administration phases.

During the test phase, the integrity of the flow set 12 is checked. Also, correct assembly of the system 10 and the presence of the correct components of the flow set 12, and particularly the valve 22, are checked. Further, the existence of air pockets or bubbles in the tubing set 16 may be detected.

A test phase sequence is shown graphically in Fig. 3. As illustrated in Fig. 3A, during a first step 50 of the test phase, the pump 14 propels a small amount of liquid, for example about 0.5 ml, in a reverse direction, and then, in a second step 52, propels another small amount of liquid, for example about 0.4 ml, in a forward direction. The pressure change, relative to atmospheric, in the downstream portion of the flow set 12 (that is between the pump 14 and the valve 22) is shown in Fig. 3B.

If the pump system 10 has no faults, the pressure change is given by the solid line in Fig. 3B. In the first step 50, the pressure drops below atmospheric. In the second step 52, the pressure increases above atmospheric. The pressure is expected, in the second step 52, to increase to the cracking (threshold) pressure of the valve 22. As mentioned above, this is typically about 20 kPa. This pressure is maintained while the pump 14 is operating. When the pump 14 is then stopped, the pressure slowly declines to the zero level. This pressure curve, the no-fault curve, forms a standard which is stored in the microprocessor.

There may be several operative faults in the pump system 10. One possible fault is reverse assembly of the valve 22 in the flow set 12. Another possible fault is the reverse engagement of the pump 14 with the flow set 12 (in which case the pump 14 in a "forward" operational state in fact propels liquid in a reverse direction). Both of these faults will result in a pressure curve which is essentially a mirror image of the standard pressure curve. This faulty pressure curve is shown in Fig. 3B by the dashed line marked I. Another possible fault is leakage in the flow set 12 or the existence of air pockets or air bubbles (e.g. as foam) in the flow set 12. In this case, the pressure changes will be more moderate pressure than that of the standard curve; this is shown in Fig. 3B by the dashed-dotted lines marked II. A further possible fault state occurs when a valve 22 with an incorrect cracking pressure is used. In this case, the pressure curve

during the first step 50 will be essentially the same as the standard curve. However, during the second step 52, the pressure will reach higher or lower maximum value than the standard curve; this is represented in Fig. 3B by dotted lines III' and III'', respectively. Yet another possible fault is where the valve 22 is omitted entirely. In this case there will be substantially no pressure change and the pressure curve will essentially follow the abscissa (marked IV in Fig. 3B).

It will be appreciated that, in the test phase, the pump 14 need not first propel liquid in the reverse direction and then in the forward direction. In particular, this sequence may be reversed such that, during the test phase, the pump 14 first propels liquid in the forward direction and then in the reverse direction. This is merely a matter of appropriately setting the control unit 15. However, in this case, the standard pressure curve should be appropriate for an inverted test sequence.

During the test phase, the pressure curve which is determined is compared to the standard pressure curve stored in the memory in the control unit 15. In the event that the determined pressure curve deviates from the standard curve, the microprocessor indicates the presence of an error. It will be appreciated that the microprocessor may permit small deviations from the standard curve prior to indicating the presence of an error.

Upon the microprocessor indicating the presence of an error, the control unit 15 may, depending upon the error detected, initiate an alarm signal and prevent the pump 14 from entering into an administration phase. This may not be necessary if the error is the existence of air bubbles or air pockets. In this case, the control unit may halt the pump 14 for a short period of time, typically about 30 seconds, to allow possible air pockets to rise up in the tubing set 16 towards the container 18. Then the control unit 15 causes the pump 15 to enter into another test phase. If this fault is not detected again, the pump 14 will then be induced to enter into an administration state.

It will be appreciated that numerous modifications may be made to the preferred embodiments without departing from the scope of the invention as set out in the claims. For example, it is not essential for a drip chamber 21 to be connected in the flow set 12. Similarly, it is not essential that the flow set 12 use a one way valve 22 as described above. Other valve types and arrangements may be used; for example a combination of a one way valve and a valve which opens upon a threshold pressure being reached.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A pump system for delivering a liquid from a container to a patient through a flow set, the system including:

a flow set comprising a tubing set connectable at one end to the container for
5 delivery of liquid to the patient, and a one-way valve system coupled to the tubing set which permits liquid flow to the patient when a pressure differential over the valve exceeds a threshold pressure, and which prevents back flow, and

a pump having

(i) a sensing means for sensing a parameter indicative of the pressure in the
10 flow set; and

(ii) a controller having a computing and memory means for determining
deviation of the parameter from a standard, the deviation being indicative of an
error in the flow set, wherein the controller causes the pump during operation of
the pump, to enter into a test phase at selected intervals, the test phase comprising
15 a first test sequence, in which the pump propels a first amount of liquid in a first
direction through the flow set, and a second test sequence in which the pump
propels a second amount of liquid in a second direction, opposite the first through
the flow set;

the sensing means sensing the parameter during the first test sequence and the second
20 test sequence.

2. A pump system according to claim 1, in which the sensing means measures
changes in the diameter of tubing in the flow set for sensing the parameter indicative of
the pressure.

3. A pump system according to claim 2 in which the sensing means is a tube diameter
25 gauge.

4. A pump system according to claim 1 in which the valve system comprises a valve
having a liquid flow path sealed by a resilient membrane, the membrane being
deformable in a desired flow direction at or above a threshold pressure for opening
perforations in the membrane to permit flow.

5. A pump system according to claim 4, in which the valve has a support preventing
30 the membrane from deforming sufficiently in an opposite flow direction for preventing
back flow.



6. A pump system according to claim 5 in which the valve system comprises a valve having a liquid flow path sealed by a resilient membrane, the membrane being deformable in a desired flow direction at or above a threshold pressure for opening perforations in the membrane to permit flow.
- 5 7. A pump system according to claim 6 in which the valve has a support preventing the membrane from deforming sufficiently in an opposite flow direction for preventing back flow.
8. A pump substantially as herein described with reference to any one embodiment and its associated drawings.
- 10 9. A pump system substantially as herein described with reference to any one embodiment and its associated drawings.
10. A method for administering a liquid substantially as herein described with reference to any one embodiment and its associated drawings.

DATED this 12th Day of December 2001

15 SOCIETE DES PRODUITS NESTLE S.A.

Attorney: PAUL G. HARRISON
Fellow Institute of Patent and Trade Mark Attorneys of Australia
of BALDWIN SHELSTON WATERS



1/3

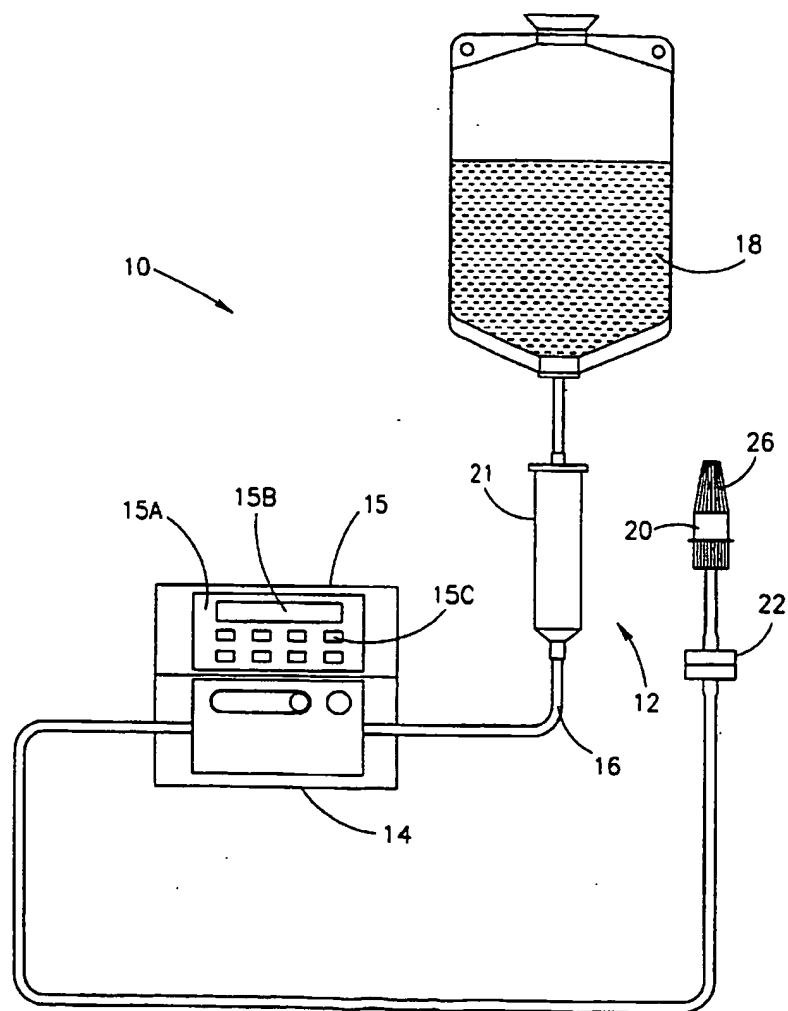


FIG. 1

2/3

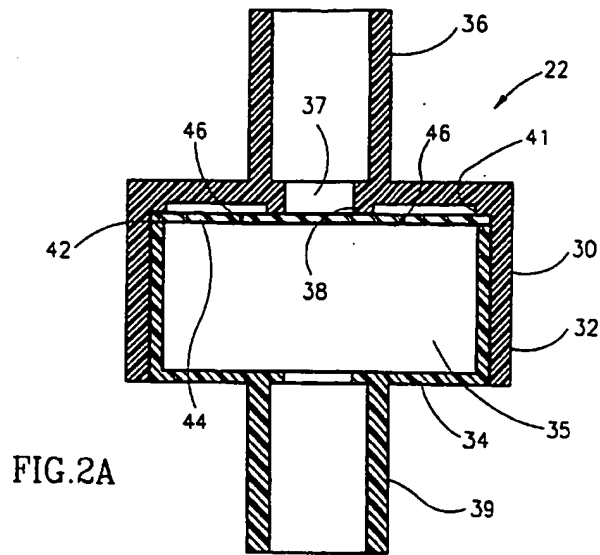


FIG. 2A

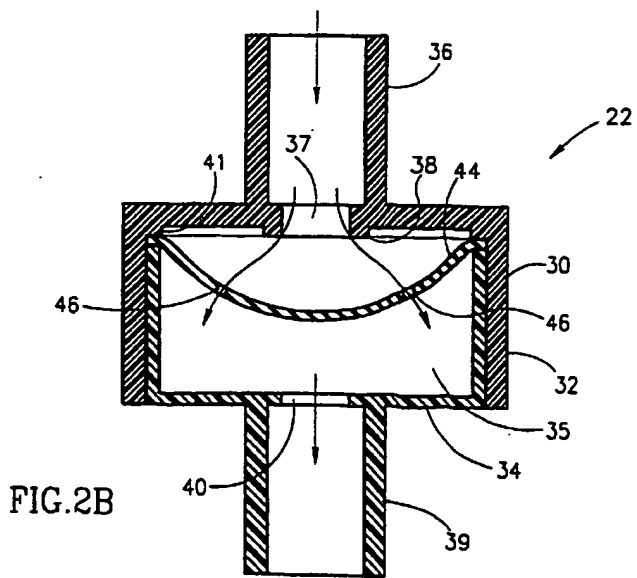


FIG. 2B

3/3

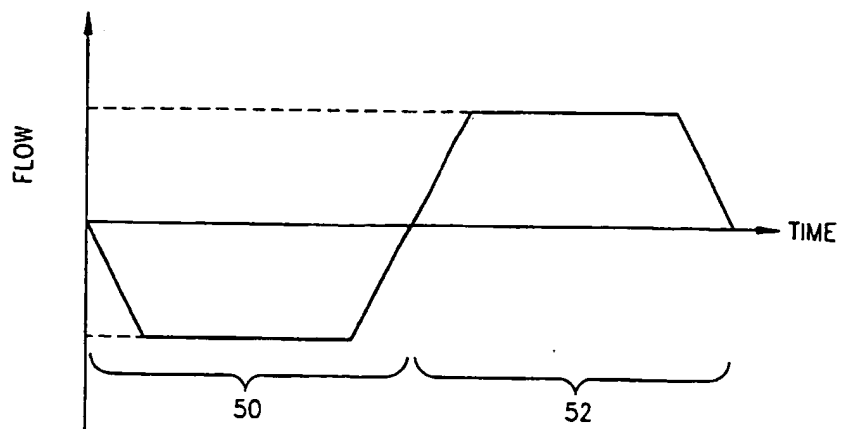


FIG. 3A

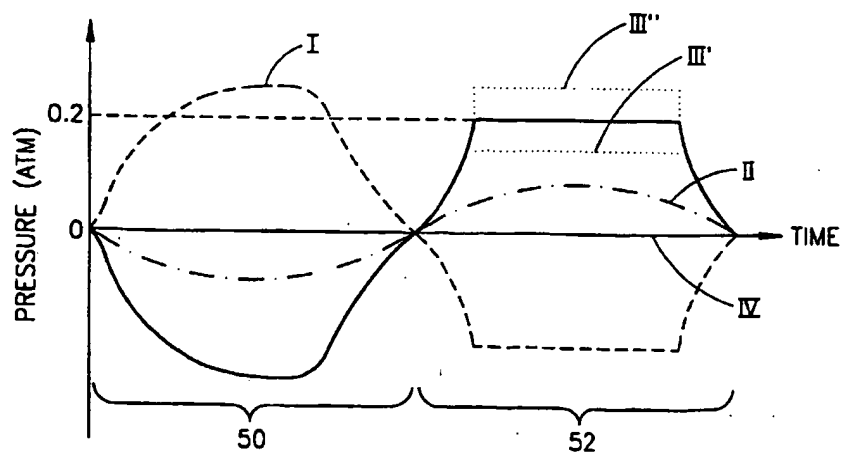


FIG. 3B